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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,395	02/08/2002	Michael L. Bell	2030-045	9989

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EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
12/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/071,395	BELL, MICHAEL L.	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5-11 and 15-35* is/are pending in the application.

4a) Of the above claim(s) *5-11 and 15-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5 October 2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 25-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25 and 26 recite incubation "under conditions sufficient to permit binding between multiple sets of binding ligands and corresponding target analyte", which is vague because it is unclear what conditions of incubation are sufficient to permit binding. The claims are read in light of the specification, however the specification does not teach the conditions required for sufficient binding.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 25-29 and 31- 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagasawa et al. (US 6,897,021) in view of Cronin et al. (US 6,045,996).

Nagasawa et al. teach a method of providing a plurality of supports, wherein for each of the multiple target analytes to be assayed, a solid support is provided which comprises a bound binding ligand capable of specifically binding to the target analyte (col. 2, lines 47-55; col. 8, lines 3-9; col. 8, lines 52-57; col. 13, lines 7-14); using the supports for detection of analyte in a sample, wherein the sample is incubated in the presence of the supports (sample is labeled and allowed to flow over the chip to bind to the receptive material, col. 1, lines 31-37; reactive probe chips are used for detection of analyte in a sample, col. 13, lines 7-14, and would therefore use the detection method described in the "background of the invention" section); and the presence of each of the target analyte to be assayed is determined by determining the extent of binding between the target analyte and the solid support bound binding ligand (detection of fluorescence is detected and quantified, col. 1, lines 34-36). Nagasawa et al. do not specifically teach the support providing a steric interference that hinders the ability to bind the binding ligand, but does not hinder the binding of other target analytes to other binding ligands. However, the specific at page 17 describes that beads preferably have a pore diameter of 50 nm and made of controlled pore glass to provide this limitation. Nagasawa et al. teach that the pores size may be 50 nm

(example 3, col. 10) and the porous material is controlled pore glass (example 3, col. 10), and therefore provide, or is capable of providing, the steric interference as recited by instant claims 25 and 26. Nagasawa et al. fail to teach incubation of the sample in the presence of the supports in a single reaction vessel.

Cronin et al. teach a biochip with a plurality of DNA binding regions (col. 3, lines 30-37) placed within a reaction vessel (contact between array and sample takes place in a container, col. 5, lines 35-38) and incubation under conditions that permit binding between multiple binding ligands on the biochip and a sample in a single reaction vessel (incubation takes place under conditions for hybridization to take place in a single container, col. 5, lines 34-51), in order to provide detection of analyte in a sample (col. 5, lines 52-58).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Nagasawa et al., placement of a plurality of supports in a plurality of reaction vessels for incubation with different samples as taught by Cronin et al., in order to provide easy introduction and removal of samples and other fluids and accurately control the incubation temperature required for hybridization.

With respect to claims 27 and 31, the pore sizes of Nagasawa et al. are the same as the pore sizes taught in the instant specification for steric interference and therefore the pores of Nagasawa et al. are capable of providing the same steric interference as that recited in the instant claims.

Regarding claims 28, 29, 33 and 34, Nagasawa et al. teach detection in the presence of a detectably labeled ligand-binding molecule and determining the presence of the label, wherein the label is a fluorescent label (col. 1, lines 31-39) and incubating the solid support in the presence of the detectably labeled binding ligand (fluorescently labeled DNA, col. 1, lines 31-37).

4. Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shipwash et al. (US 2005/0164264, provisional application filed August 2000) in view of Nagasawa et al. (US 6,897,021).

Shipwash et al. teach a method comprising: providing a plurality of solid supports (different biomolecules bound to different types of microspheres, par. 185), wherein a solid support comprises a bound binding ligand capable of specific binding to each of a multiple target analytes to be assayed (multiple labels are used to detect multiple analyte, par. 44 and 185) and the solid support may be a porous bead (par. 264); incubating a sample in the presence of the supports under conditions sufficient to permit binding between multiple sets of binding ligands (binding assays are performed in the reaction vesicle, therefore an incubation occurs under conditions that provide binding for all analyte of interest, par. 185) and corresponding target analytes in a single reaction vessel (plurality of binding assays performed in the same reaction vesicle, par. 185); and determining for each of the multiple target analytes to be assayed the presence or absence of the target analyte by determining the extent of binding between the target analyte and the solid support bound binding ligand (par. 185). Fulton fails to teach the ability of the target analyte to bind to the binding ligand of the support hindered by steric interference that does not hinder the binding of other target analytes.

Nagasawa et al. teach binding ligands bound within porous particle structures (col. 6, lines 25-33; col. 2, lines 46-55) and a pore size of 50 nm (example 3, col. 10), in order to provide a pore size that allows diffusion of the detection target through the porous material. Nagasawa et al. do not specifically teach the support providing a steric interference that hinders the ability to bind the binding ligand, but does not hinder the binding of other target analytes to other binding ligands. However, the specific at page 17 describes that beads preferably have a pore diameter of 50 nm and made of controlled pore glass to provide this

limitation. Nagasawa et al. teach that the pores size may be 50 nm (example 3, col. 10) and the porous material is controlled pore glass (example 3, col. 10), and therefore provide, or is capable of providing, the steric interference as recited by instant claims 25 and 26.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Shipwash et al., ligands immobilized within the pores and a specific pore size of 50 nm as taught by Nagasawa et al., in order to prevent side-reaction with contaminants and a larger reactive surface area which allows for more accurate detection.

Regarding claims 30 and 35, Shipwash et al. teach detection of the microspheres using flow cytometry (par. 187 and 278-279).

Response to Arguments

1. Applicant's arguments with respect to claims 25-35 have been considered but are moot in view of the new ground(s) of rejection. The previous rejections of the claims have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of applicant's amendment requiring the new limitation of incubation and binding in a single reaction vessel.

Applicant argues that Nagasawa et al. teach each porous region having a different binding ligand present in different compartments and therefore the incubation cannot occur in a single reaction vessel. In response to applicant's arguments, although the supports comprising ligands for different analyte are separated into different compartments, the supports are present on the same biochip (col. 2, lines 47-55) and when the biochip is placed in a container for contact with the sample as taught by _ et al., the incubation occurs in the same reaction vessel. Furthermore, Nagasawa et al. teach that the plurality of regions are simultaneously contacted with a sample (col. 5, lines 63-67) and also teach an

embodiment comprising micro compartments that are not materially separated and are instead present on the substrate in imaginary compartments (col. 7, lines 27-37).

Applicant's arguments regarding the rejection of Nagasawa in view of McHugh are persuasive and the previous rejection has been withdrawn.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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